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10/531,476	04/15/2005	Stefan Madaus	PTB-4750-27	6503

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EXAMINER	
TOTH, KAREN E	
ART UNIT	PAPER NUMBER
3735	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,476	MADAUS ET AL.	
	Examiner	Art Unit	
	KAREN E. TOTH	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *34-36* is/are allowed.

6)☒ Claim(s) *1-8,10-14,17,18,21,22,24-31 and 33* is/are rejected.

7)☒ Claim(s) *9,15,16,19,20,23 and 32* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In line 2 the claim states that the measurement signal is related to "respiration activity", while in lines 6-7 the measurement signal is referred to as being related to "respiratory gas flow". For the purposes of examination the claim will be treated as though both instances refer to "respiration activity".

4. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: the relationship between the breathing mask and the breathing mask device. Neither is described in the specification, and it is not clear what would be present in a breathing mask device to make it distinguishable from a breathing mask.

Claim Rejections - 35 USC § 102

5. Claims 27 and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Watson (US 4777962).

Regarding claim 27, Watson discloses an evaluation apparatus for evaluating measurement data indicative of breathing patterns comprising a signal processing device (element 26) that performs differentiation of a respiratory cycle signal to generate evaluation results that can distinguish between central and obstructive breathing disorders (column 4, lines 37-67).

Regarding claim 28, Watson further discloses a display (element 28) showing the results.

Claim Rejections - 35 USC § 103

6. Claims 1, 2, 8, 10-14, 24-26, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman (US 6287264) in view of Watson.

Regarding claims 1 and 24, Hoffman discloses a method of processing measurement signals related to a patient's respiration activity while regulating the administration of a breathable gas pressurized to higher than ambient pressure (figure 17) comprising evaluating the measurement signal, including analyzing the signal in order to identify a disorder (column 7, lines 21-30). Hoffman does not disclose the evaluation including differentiation of the signal nor the results permitting classification between central and obstructive breathing disorders. Watson teaches obtaining measurement signals related to a patient's respiration activity, and performing differentiation on the signals in order to perform classification between central and

obstructive breathing disorders (column 4, lines 37-67), in order to allow optimization of treatment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Hoffman and performed differentiation of the signal to distinguish between central and obstructive disorders, as taught by Watson, in order to optimize treatment.

Regarding claim 2, Hoffman further discloses detecting inspiration and expiration times for successive breaths (figures 8A-D).

Regarding claims 8 and 30, Watson's first derivative results are extracted over a plurality of respiratory cycles and the results present successively occurring changes (column 4, lines 37-67), in order to determine changes in the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have found successively occurring changes over a plurality of respiratory cycles, as taught by Watson, while performing the method of Hoffman in view of Watson, in order to determine changes in the patient's condition.

Regarding claim 10, since differentiation is the process of finding the slope of a curve, Hoffman in view of Watson is inherently directed to finding curve shape.

Regarding claims 11 and 12, Watson discloses taking the derivative of the entire respiratory signal, which includes selected intervals and phase changes; the broadest reasonable interpretation of the term "gradient" is a slope, which is what is found by taking a derivative, since Applicant has not provided any more specific definition of the term (column 4, lines 37-67), in order to accurately distinguish between disorders. It would have been obvious to one of ordinary skill in the art at the time the invention was

made to have followed Hoffman in view of Watson and found various gradients of the signal, as taught by Watson, in order to accurately distinguish between disorders.

Regarding claim 13, identification of central breathing disorders inherently displays analysis of the breathing drive's constitution and nature.

Regarding claim 14, Hoffman further discloses finding breath volume (column 16, lines 61-66).

Regarding claim 25, Hoffman discloses an apparatus for supplying pressurized respiratory gas to a patient comprising a delivery device (figure 17; element 828), a measuring device for generating a signal indicative of respiratory gas flow (elements 802, 804), a device for regulating the pressure of the gas (elements 812, 842, 844, 852 – CPAP is inherently delivered at a particular pressure), a device for presetting the pressure (element 812), and a signal processing device configured to generate an evaluation result based on variation in respiratory-cycle features that is then used to set the pressure (column 7, lines 21-30). Hoffman does not disclose the evaluation result being obtained via differentiation, nor being used to distinguish between central and obstructive disorders. Watson teaches obtaining measurement signals related to a patient's respiration activity, and performing differentiation on the signals in order to perform classification between central and obstructive breathing disorders (column 4, lines 37-67), in order to allow optimization of treatment. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Hoffman and performed differentiation of the signal to distinguish between central and obstructive disorders, as taught by Watson, in order to optimize treatment.

Regarding claim 26, Hoffman further discloses a respiratory gas line extending between the delivery device and a breathing mask (figure 17).

Regarding claim 31, the Examiner notes that Watson does not expressly disclose calculating the gradient over 10% of the breathing phase's duration. However, at the time the invention was made, it would have been an obvious matter of design choice for a person of ordinary skill in the art to calculate the gradient over 10% of the breathing phase because Applicant has not disclosed that a period of 10% provides a particular advantage, is for a particular purpose, or solves a stated problem. Moreover, it appears that the time period of Watson, or Applicant's time period, would perform equally well to distinguish between breathing disorders. Accordingly, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified Hoffman in view of Watson such that the gradient was calculated over 10% of the breathing phase, because such a modification would have been a mere design consideration that fails to patentably distinguish over Hoffman and Watson.

7. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman in view of Watson, as applied above, and further in view of Berthon-Jones (US Patent 6029665).

Regarding claim 18, Hoffman in view of Watson discloses all the elements of the claimed invention, as described above, except for performing an evaluation of the nature and constitution of the patient's upper respiratory tracts. Berthon-Jones teaches a method of respiratory monitoring to distinguish between types of breathing disorders

comprising monitoring the patency of the patient's upper respiratory tracts (column 3, lines 25-52; column 9, lines 54-57), in order to determine the origin of a respiratory disorder. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Hoffman in view of Watson and monitored the condition of the patient's upper respiratory tracts, as taught by Berthon-Jones, in order to determine the origin of a respiratory disorder.

8. Claims 3-6, 7, 17, 21, 22, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman in view of Watson, as applied above, and further in view of Rapoport (US Patent 5335654).

Regarding claims 3, 4, 6, 7, 17, 21, and 22, Hoffman in view of Watson discloses all the elements of the claimed inventions, as described above, except for using the ratio of inspiratory and expiratory flow times to determine the origin of a breathing disorder. Rapoport teaches a method of monitoring breathing to determine the origin of a breathing disorder comprising finding inspiratory and expiratory flow times and their ratio, and using that ratio to determine if a breathing disorder is obstructive (column 4, lines 25-45), in order to effectively treat the patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed the method of Hoffman in view of Watson and found and used an inspiratory/expiratory time ratio to determine the origin and characteristics of a breathing disorder, as taught by Rapoport.

Regarding claims 5 and 29, Watson's evaluation results are generated from successively occurring changes in the first derivatives (column 4, lines 37-67).

Allowable Subject Matter

9. Claims 9, 15, 16, 19, 20, 23, and 32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art of record fails to anticipate or make obvious the invention of claim 9, including, *inter-alia*, differentiating a respiratory activity signal to distinguish between obstructive and central breathing disorders by extracting evaluation results for an existing or imminent disturbance from successively occurring changes in the signal's derivatives at the beginning and/or end of the inspiratory phase of a breathing cycle.

The prior art of record fails to anticipate or make obvious the invention of claims 15, 16, and 32, including, *inter-alia*, differentiating a respiratory activity signal to distinguish between obstructive and central breathing disorders by extracting evaluation results from the signal's derivatives at the beginning and/or end of the expiratory phase of a breathing cycle.

The prior art of record fails to anticipate or make obvious the invention of claim 19, including, *inter-alia*, differentiating a respiratory activity signal to distinguish between obstructive and central breathing disorders, where processing the signal comprises analyzing the shape of the signal's curve to find the number of local maxima and minima, the amplitude of the local maxima and minima, the sequence of the magnitudes

of the amplitudes of the local maxima and minima, and the frequency of the sequence of the local maxima and minima.

The prior art of record fails to anticipate or make obvious the invention of claim 20, including, *inter-alia*, differentiating a respiratory activity signal to distinguish between obstructive and central breathing disorders, where processing the signal comprises spectral analysis and analysis of the amplitude of a snoring signal.

The prior art of record fails to anticipate or make obvious the method of claims 23 and 33, including, *inter-alia*, differentiating a respiratory activity signal to distinguish between obstructive and central breathing disorders comprising performing an evaluation procedure that generates information about the nature of a patient's upper respiratory tracts that differentiates between central and obstructive apneas, the elastic properties of the respiratory tracts, the location of an obstruction, the degree of severity of an apnea, and the patient's Pcrit (critical collapse pressure) value.

10. The following is a statement of reasons for the indication of allowable subject matter:

The prior art of record fails to anticipate or make obvious the invention of claim 34, including, *inter-alia*, processing a respiratory activity signal to differentiate between obstructive and central breathing disorders, where the processing comprises analyzing the shape of the signal's curve to find the number of local maxima and minima, the amplitude of the local maxima and minima, the sequence of the magnitudes of the

amplitudes of the local maxima and minima, and the frequency of the sequence of the local maxima and minima.

The prior art of record fails to anticipate or make obvious the invention of claim 35, including, *inter-alia*, processing a respiratory activity signal to differentiate between obstructive and central breathing disorders, where the processing comprises spectral analysis and analysis of the amplitude of a snoring signal.

The prior art of record fails to anticipate or make obvious the method of claim 36, including, *inter-alia*, processing a respiratory activity signal to differentiate between obstructive and central breathing disorders comprising performing an evaluation procedure that generates information about the nature of a patient's upper respiratory tracts that differentiates between central and obstructive apneas, the elastic properties of the respiratory tracts, the location of an obstruction, the degree of severity of an apnea, and the patient's Pcrit (critical collapse pressure) value.

The allowability of these claims has been discussed in the previous Office Action.

Response to Arguments

11. Applicant's arguments with respect to claims 1-28 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6165133 to Rapoport, US 6015388 to Sackner, US 2004/0230105 to Geva, and 5704345 to Berthon-Jones, which disclose similar inventions.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Mon thru Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Patricia C. Mallari/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735